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JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER ANDERSON, JAMES D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	09/704,054		D'AMATO, ROBERT	
	Examiner		Art Unit	
	James D. Anderson		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25-31,33-40,59-62,71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25-31,33-40,59-62,71 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>13 sheets</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 23, 25-31, 33-40, 59-62, and 71-72 are presented for examination

Applicants' amendment filed 10/31/2007 has been received and entered into the application. Accordingly, claims 23, 34, and 71 have been amended and claim 72 has been added.

Applicants' arguments, filed 10/31/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 11/7/2007. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

The following references cited on the IDS filed 11/7/2007 were not considered because they are missing a date of publication: citations C26, C59, C78, C114, C147, C156, C159, C177, C180, and C198.

Response to Arguments

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. With respect to the 35 U.S.C. 112, 1st Paragraph (Enablement) rejection, Applicants

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have amended the claims to now recite the inhibition of growth of blood-borne tumors comprising administering thalidomide. The Examiner has considered Applicant's arguments and amendments to the claims but is not persuaded that Applicant is enabled for the treating any and all blood-borne tumors with thalidomide. Applicant's arguments primarily reiterate arguments made in the response filed 7/12/2007, to which the Examiner responded in the Office Action mailed 7/31/2007. Accordingly, the Examiner refers to his previous response for a full discussion of the state of the art of treating cancer with thalidomide.

Applicant argues that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied (emphasis in original). The basis of this argument appears to be that since thalidomide inhibits angiogenesis and angiogenesis is correlated to tumor growth, the specification necessarily discloses a method of making and using the invention that correlates to the entire scope of the claims. However, the fact that a particular compound inhibits angiogenesis in a model of angiogenesis does not, *a priori*, mean that said compound necessarily inhibits the growth of tumors as instantly claimed. In fact, the Examiner has provided substantial prior art evidence that thalidomide is not effective in treating cancer or inhibiting tumor growth. Applicant is reminded that the unpredictability of the art is one factor to be considered in establishing lack of enablement under 35 U.S.C. § 112, 1st Paragraph (*In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404). Secondly, it was well known in the art prior to Applicant's invention that angiogenesis is involved in tumor growth. Further, as evidenced by the prior art cited by the Applicant and the Examiner, thalidomide had been administered to both animals and humans for the treatment of cancer and tumors well before Applicant's invention

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(see Grabstald *et al.*, 1965; Olsen *et al.*, 1965; Roe *et al.*, 1963; Bach *et al.*, 1963; DiPaolo *et al.*, 1964; and DiPaolo *et al.*, 1963). In fact, were it not for the entirely unpredictable nature of the claimed invention, the present claims would be clearly obvious in view of the prior art.

However, because such administration of thalidomide to humans and animals was shown to not be effective, the art cannot be said to render obvious the claimed invention because there would simply be no reasonable predictability or expectation of success.

Applicant next argues that the prior art as a whole supports the use of thalidomide for inhibiting tumors, based on the discovery of the present inventor that thalidomide inhibits angiogenesis. However, well prior to Applicant's discovery of this mechanism of thalidomide action, the prior art attempted to use thalidomide to treat cancer and inhibit tumor growth. In fact, it was well established in the prior art that thalidomide was not effective at inhibiting tumor growth and skilled artisans in the field gave up trying to develop thalidomide for this purpose (see Grabstald *et al.*, 1965; Olsen *et al.*, 1965; Roe *et al.*, 1963; Bach *et al.*, 1963; DiPaolo *et al.*, 1964; and DiPaolo *et al.*, 1963). Again, the prior art would be anticipatory, or at least render obvious the claimed invention, if administration of thalidomide to inhibit tumor growth or treat cancer actually worked. The fact remains that the claimed methods are entirely unpredictable and will likely not work for even a reasonable number of tumors, despite the guidance and direction Applicant provides in the specification.

Applicants additionally submit that because thalidomide has been shown to be effective in treating multiple myeloma (and is approved by the FDA for such treatment), then the treatment of "blood-borne tumors" with thalidomide is fully enabled. However, given the fact that this is the only tumor for which thalidomide has been shown to be effective, coupled with

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the fact that the art cited by the Examiner teaches that thalidomide is generally ineffective in treating cancer, one skilled in the art would not reasonably expect thalidomide to be effective in treating any other blood-borne tumors other than multiple myeloma. Further, the art of treating cancer is generally unpredictable and an agent effective at treating one type of cancer is not, a priori, predicted to have efficacy in treating other cancers. For example, despite the fact that there are numerous anticancer drugs used clinically, no one drug is used to treat different types of cancer. Accordingly, the claims are deemed properly rejected under 35 U.S.C. 112, 1st Paragraph as lacking enablement for treating "blood-borne tumors" generally with thalidomide.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 25-31, 33-40, 59-62, and 71-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating multiple myeloma, does not reasonably provide enablement for treating "blood-borne tumors". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

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In re Wright, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *PPG v. Guardian*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) The breadth of the claims.

¹ As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

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These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to inhibiting the growth or metastasis of blood-borne tumors sensitive to thalidomide in a human comprising the administration of thalidomide. The relative skill of those in the art is high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the unpredictable nature of the art.

It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain). As illustrative of

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the state of the art with respect to animal models of cancer, the examiner cites Sausville *et al.* (Cancer Research, 2006, vol. 66, pages 3351-3354) and Johnson *et al.* (British J. of Cancer, 2001, 84(10):1424-1431).

Sausville *et al.*, cited for evidentiary purposes, teaches that traditionally explored tumor model systems are insufficient to predict how actual human beings will respond to treatment in the clinic (page 3351, left column). Even when drugs with evidence of anticancer activity in preclinical *in vivo* models are given their maximum tolerated dose in humans, they frequently fail to produce useful activity in humans (*id.*). Also, with regard to unpredictability, Johnson *et al.*, also cited for evidentiary purposes, teach that the *in vivo* activity of 39 different agents in a particular histology in a tumor model did not correlate to activity in the same human cancer. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

As illustrative of the state of the art with respect to administering thalidomide to inhibit tumor growth, the examiner cites Bach *et al.* (Acta Path., 1963, 59:491-499) (cited by applicant), Gutman *et al.* (Anticancer Research, 1996, 16:3673-3677), DiPaolo (Cancer Chemotherapy Reports, 1963, 29:99-102) (cited by applicant), Thomas *et al.* (Current Opinion in Oncology, 2000, 12:564-573) and Grabstald *et al.* (Clinical Pharmacology and Therapeutics, 1965, 6:298-302) (cited by applicant). All references are cited for evidentiary purposes only.

Bach *et al.* studied the possible antineoplastic effect of thalidomide in experimental mouse models. The reference also discusses a report in which a woman with an X-ray resistant pelvic tumors was treated with thalidomide (400 mg daily). The tumors increased in size during the treatment. Bach *et al.* transplanted NJA tumors (a transplantable leukemia) and PBH tumors

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(an adenocarcinoma) in mice (page 494). The mice were then treated with varying doses (11.2, 112.0, 560.0 and 1120.0 mg/kg) of thalidomide (page 495). In mice with PBH tumors, all thalidomide treated mice died before controls (pages 496-497). In the NJA implanted mice, there was no significant effect of thalidomide on the survival times of the animals. Further, histological exam revealed no difference with regard to the extent of the leukemic infiltrations in the organs between treated and untreated mice (pages 496-497). The authors conclude that thalidomide had no antineoplastic effect (page 498).

Gutman *et al.* tested the efficacy of thalidomide in treating solid tumors in mice (Abstract). B16-F10 (melanoma) and CT-26 (colon carcinoma) cells were injected in mice and the mice then received 0.3-1.0 mg thalidomide (*id.*). There was no growth retardation in CT-26 bearing mice or in mice with pulmonary or peritoneal metastases of B16-F10 melanoma (*id.*). All tumors reached maximum size, similar to controls. Further, morphological exam revealed that in both thalidomide and control groups, all mice had developed an intact network of new blood vessels (*id.*). In conclusion, the authors report that the present study did not demonstrate a sustained, reproducible, anti-angiogenic effect of thalidomide in solid tumors growing in mice (page 3676).

DiPaolo also studied the effects of thalidomide in treating standard rat and mouse tumors, including adenocarcinoma, Ehrlich ascites, leukemia, sarcoma, Murphy-Sturm, lymphosarcoma and Walker 256 (Table 1). The daily dose of thalidomide was 500 mg/kg (*id.*). Based on the results of this study, DiPaolo concludes, “thalidomide is ineffective against transplantable cancers” (page 102).

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Thus, in three separate studies, thalidomide was ineffective in inhibiting tumor growth in mouse models of cancer. Given this information, the skilled artisan would not reasonably expect thalidomide to be effective in treating tumors in humans.

Grabstald *et al.* is cited as evidence to support the unpredictability of treating tumors in humans using thalidomide. In fact, Applicant admits that Grabstald *et al.* teach away from the present invention (see Response filed January 27, 2005). The reference teaches that thalidomide was administered to 71 patients with a wide spectrum of cancers (Abstract). There was no evidence of an objective response in any cancer except one patient with renal cell cancer (*id.* at page 301). The authors conclude, “further random trials of this [thalidomide] drug against cancer in man are not indicated” (page 301). It is noted that Grabstald *et al.* would clearly render obvious the claimed invention if the reference provided some reasonable predictability or expectation of success.

Thomas *et al.* provides a review of the current role of thalidomide in cancer treatment. Although the article will not be discussed in detail, several points are pertinent to the present rejection. Firstly, the article states that the first oncology studies of thalidomide were reported in 1965 (Grabstald *et al.*, cited *supra*). Further, another study of 21 patients with various solid tumors who were treated with thalidomide revealed no tumor regressions (page 564). Secondly, several clinical trials of thalidomide have been carried out (pages 566-569). Thalidomide has shown moderate effects in some cancers (gliomas – 2/36 patients had partial response, 2/36 patients had a minor response, and 12/36 had stable disease; Kaposi’s sarcoma – 6/17 patients had a partial response, 8/17 patients withdrew from toxicity; renal cell carcinoma – 3/18 patients had partial response) (pages 566-567). However, there were no objective tumor responses in 63

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patients with metastatic prostate cancer, no objective responses in 17 patients with melanoma, no objective responses in 12 patients with breast cancer or 19 patients with ovarian carcinoma, and no objective tumor responses in 17 patients with metastatic squamous cell carcinoma of the head and neck (in fact, 94% of patients had progressive disease) (pages 567-568). Thirdly, a summary of FDA new drug applications issued for thalidomide between 1997 and 1998 yielded data on 480 patients treated for breast, CNS, prostate, skin, colon, pancreas and kidney malignancies. Thalidomide was given in doses up to 2400 mg daily. Responses were observed in 36 patients (7.5%), 10 of who had received combination therapy (*i.e.* not thalidomide alone), whereas 53% of patients discontinued therapy because of toxicity (page 568). Thus, it is clear that the treatment of tumors in humans with thalidomide is extremely unpredictable and in the majority of cases completely ineffective.

Applicants own admissions on the record provide further evidence that the treatment of tumors in humans with thalidomide is entirely unpredictable. For example, in Applicant's response filed 8/7/2006, applicant submitted that 19 references "indicate that thalidomide was not successful in inhibiting tumors in animals and humans" (page 16 of response filed 8/7/2006). Further, Applicant states (emphasis added), "Moreover, Applicant respectfully points out that several references actually teach that thalidomide has cancer-promoting or carcinogenic activity" (*id.*). Further still, Applicant states (emphasis added), "The references disclose not only failure but the complete opposite effect to the claimed invention" (*id.*). Applicant goes on to cite several studies wherein thalidomide was administered to humans with various tumors. Applicant concludes (emphasis added), "Again, all of these studies failed to provide any promise for thalidomide as effective in inhibiting the formation or growth of tumors in

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humans. The studies neither provide with any suggestion, **nor a reasonable expectation of success in inhibiting tumors in humans**" (*id.* at page 17). Thus, it is clear that thalidomide may actually promote cancer in some instances and in fact may have the opposite effect to that instantly claimed.

Thus, a preponderance of evidence suggests that treating tumors with thalidomide, particularly in humans, is extremely unpredictable and in most cases ineffective. Further, it is evident that thalidomide may actually have the complete opposite effect than those instantly.

2. The breadth of the claims

The claims vary in breadth; some (such as claim 23) vary broadly, reciting the prevention or inhibition of growth of any and all tumors sensitive to thalidomide (both benign and cancerous) by administering thalidomide. Conspicuously absent from the disclosure, however, is any indication exactly which human tumors are sensitive to thalidomide. As evidenced by the references cited *supra*, most human cancers and tumors are **not** sensitive to thalidomide treatment. Others, such as claim 34, are narrower, reciting specific tumors. All, however, are extremely broad insofar as they disclose the general prevention, growth inhibition and inhibition of metastases of tumors with thalidomide.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimens (*e.g.*, dosages, timing, administration routes, etc.) necessary to treat all of the various tumors claimed, particularly in humans. The working examples are limited to

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demonstrating the anti-angiogenic activity of thalidomide in animal models of angiogenesis.

While angiogenesis is one factor involved in tumor growth, there are many other factors that influence tumor growth. As such, the fact that thalidomide inhibits angiogenesis does not reasonably suggest that it will be effective in inhibiting tumor growth. In fact, as discussed *supra*, the prior art supports the idea that thalidomide is ineffective in inhibiting tumor growth in humans and therefore supports the Examiner's position that the working examples do not correlate to inhibition of tumor growth, let alone prevention of tumors or inhibition of tumor metastasis. Thus, the Applicant at best has provided specific direction or guidance only for the inhibition of angiogenesis with thalidomide. Although broad doses and administration routes of thalidomide are described in the specification, these doses and administration routes are contemplated to be useful for the treatment of any all angiogenic-related conditions. No reasonably specific guidance is provided concerning useful therapeutic protocols for any specific conditions or diseases, particularly the treatment of tumors.

Further, there are no *in vitro* or *in vivo* experimental models of any diseases described, including cell proliferation or animal tumor models. While the administration routes disclosed in the specification are standard routes of administration for therapeutic agents, Applicant has provided no specific administration regimens (*e.g.* timing, specific doses, etc.) necessary to prevent, inhibit the growth of or inhibit metastases of any specific tumors. Finally, while Applicant recites a broad dose range (0.1 to 300 mg/kg/day), this dose range is not reasonably specific enough so as to provide adequate guidance to the skilled artisan in the treatment of tumors, especially considering that doses within this range have previously been administered to inhibit tumor growth or treat cancer and were entirely ineffective.

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4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that thalidomide could be predictably used to prevent all tumors, inhibit the growth of all tumors and/or inhibit the metastasis of all tumors sensitive to thalidomide as inferred in the claims and contemplated by the specification. A preponderance of the evidence suggests that thalidomide is ineffective in treating tumors in humans. Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038.

The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


James D. Anderson
Patent Examiner
AU 1614

January 8, 2008

 1/12/08
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER